NOV - 2 2005 K052507 September 8, 2005

510(k) SUMMARY FOR FREEDOM OF INFORMATION

TYRO™-97 (hofocon A) RIGID GAS PERMEABLE
SPHERICAL, ASPHERIC, TORIC AND BIFOCAL CONTACT LENS
FOR DAILY WEAR

1. Submitted by:

The Lagado Corporation
2890 South Tejon St
Englewood, CO 80110

Contact: John M. Szabocsik, Ph.D.
Official agent
Szabocsik and Associates
203 N. Wabash, Ste 1200
Chicago, IL 60601
(312) 553-0828

2. Date prepared: September 8, 2005

3. Device:
Common Name: TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses for Daily Wear

Trade Name: TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses for Daily Wear

4. Classification: Class II (Performance Standards)
21 CFR 886.5916 (b) (1)
Rigid Gas Permeable Contact Lens for Daily Wear

5. Substantial Equivalence: This product is substantially equivalent to other currently marketed rigid lenses, such as Oxycon (wilofocon A) Rigid Gas Permeable Contact Lenses

6. Device Description

The TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses for Daily Wear are available in spherical, aspherical and toric designs in the clear untinted or blue, green and gray tinted varieties with and without UV-blocker. Each is a shell of the following dimensions.

Spherical Contact Lens:

Horizontal Lens Size:	6.5 mm to 11.50mm
Base Curve:	6.50mm to 9.50mm
Distance Powers:	+12.00D to -20.00D
Center Thickness:	
for low minus	0.05mm to 0.30mm
for plus	0.10mm to 0.70mm

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Aspheric Lens

Eccentricity	-1.5 to 1.5 Oblate to prolate
Peripheral Curves	0.1 to 1.0mm

Toric Lens

Axis	1 to 180 degrees in 1 degree steps
Cylinder power	0.50 to 4.00D

Translating Bifocal Contact Lens:

Horizontal Lens Size:	8.00mm to 10.50mm
Base Curve:	6.50mm to 8.50mm
Distance Power:	+12.00D to -20.00D
Add Power	1.00D to 4.00D

The lens material, hofocon A, is a polymer of trifluoroethyl methacrylate and silicone methacrylate, with no methyl methacrylate. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2, and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber, NORBLOC 7966. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

7. Intended use:

The TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism.

The lenses may be disinfected only by using chemical disinfection

8. Comparison to predicate devices: see following table

SUBSTANTIAL EQUIVALENCE

	OXYCON (wilofocon A)	TYRO™-97 (hofocon A)
Water Content	<1%	<0.2%
Oxygen Permeability	$26x10^{-11}$ Fatt Units(1990)	97.98 ANSI units
Refractive Index	1.44	1.440
Hardness	D/89 (Shore)	D/82 (Shore)
Specific Gravity	1.25	1.087
Residual Monomers		no leachable monomers detected
Wetting Angle	23.0±2 (CLMA method)	23.3° (sessile drop technique)
Mechanical (flexural) Strength		3952psi
Light Transmittance		
clear	93%	>95% T
blue	87%	>70% T
green		>70% T
Blue-UV		>70% T (400-780nm) 0% T (200-380nm)

Introduction

The TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic, or presbyopic and which may exhibit corneal astigmatism.

Contained in the submission are comparisons of the product to the predicate device, information on the chemistry and manufacturing, results of toxicological tests and the report of clinical trials.

I. Chemistry and Manufacturing

The lens material, hofocon A, is a polymer of trifluoroethyl methacrylate and silicone methacrylate, with no methyl methacrylate. The blue tinted lenses contain D&C Green No. 6; the green lenses contain D&C Green No 6 and CI Solvent Yellow 18; the gray lenses contain D&C Green No 6, D&C Violet No. 2,

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and CI Solvent Yellow 18; the blue-UV lenses contain D&C Green No 6 and a UV absorber, NORBLOC 7966. The colorants are used in quantities approved for use in contact lenses and proportions required to obtain the desired color.

Material and lenses are manufactured in the same manner as the predicate device, and details are contained in K990895.

II. Toxicology

The toxicological testing is summarized below.

A. Agar Overlay Cytotoxicity:
B. Systemic toxicity:
C. Acute Ocular irritation:

The lens material was shown to be non-toxic in all tests.

III. Microbiology

The material has a water content less than 1%, and is therefore exempt from the microbiological requirements for hydrophobic contact lenses.

IV. Clinical Studies

The safety of the TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses has been confirmed through a clinical trial for daily wear contact lens materials according to the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses (May 1994).

OVERALL CONCLUSION OF THE CLINICAL STUDY:

The data of the clinical trials demonstrate the safety of the TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2005

The Lagado Corporation
c/o John M. Szabocsik, PhD
Szabocsik and Associates
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

Re: K052507
Trade/Device Name: TYRO-97 (hofocon A) Rigid Gas Permeable Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: September 8, 2005
Received: September 13, 2005

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K_____

September 8, 2005

510(k) NUMBER (IF KNOWN) K052507

DEVICE NAME TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens for Daily Wear

INDICATIONS FOR USE

The TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses are indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism.

The lenses may be disinfected only by using chemical disinfection

Prescription Use X OR Over-The-Counter-Use ___
(Part 21CFR 801 Subpart D) (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K052507